

REMARKS

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow.

Claims 26, 28-50, 53, 54 116 and 121 are pending in the application, Claim 121 having been added above.

By the above amendments, new Claim 121 is added to further define an exemplary embodiment. Support for new Claim 121 can be found at least in Claim 116.

Applicants thank the Examiner for the courtesies extended to their representatives, Norman H. Stepno and Martin A. Bruehs, during the personal interview on April 6, 2005. In particular, Applicants thank the Examiner for indicating that further consideration would be given to Applicants' remarks.

Turning now to the Official Action, Claims 26, 28, 32-34, 45, 46, 51, and 116 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 93/14084. For at least the reasons that follow, withdrawal of the rejection is in order.

Independent claim 116 recites a cosmetic or dermatological method for treating sensitive skin of an individual in need of such treatment, said sensitive skin having such amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia caused by the release of substance P therein, said sensitive skin being characterized by exhibiting at least one symptom selected from the group consisting of tingling, prickly, itching, pruritus, overheating, discomfort, tugging sensations, desquamation and erythema; said method comprising topically applying to said sensitive skin having such amount of substance P already released

therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P, and said at least one substance P antagonist being formulated into a topically applicable, cosmetically/dermatologically acceptable medium therefor. (Emphasis added.)

It is well established that in order to demonstrate anticipation under 35 U.S.C. §102(b), each element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 218 USPQ 789 (Fed. Cir. 1983). That is not the case here.

For example, WO '084 fails to disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin that includes topically applying to said sensitive skin having such amount of substance P already released therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of already released substance P, as defined in independent claim 116. (Emphasis added.) That is, Applicants submit that WO '084 simply fails to disclose or suggest treating skin wherein an amount of already released therein. It cannot be shown that the skin being treated in WO '084 necessarily has an "amount of already released substance P," as recited in Claim 116. If necessary, Applicants may be willing to provide further evidence and/or testimony to support this position.

Accordingly, Applicants submit that WO '084 fails to expressly or inherently describe each element of the claims in issue, and therefore fails to anticipate claim 116.

In addition, as discussed during the personal interview of April 6, 2005, WO '084 is directed to antagonizing binding or interaction of substance P with NK₂ receptors. However, NK₂ receptors are found in the smooth muscle not in the skin. (See, for example, Abstract, Bianchi et al., J. Eur. Acad. Dermatol Venereol., 1999 Jan. 12(1):6-10, provided in the parent application, which demonstrates that only NK₁ receptors are found in human skin.) Thus, Applicants submit that the Official Actions rejections of the claimed method over WO '084 should be withdrawn for at least the additional reason that the compositions of WO '084 would not function effectively to treat sensitive skin, as claimed.

For at least these reasons, claim 116 is patentable over WO '084. Because the remaining claims (26, 28-50, 53 and 54) depend, either directly or indirectly, from independent claim 116, the remaining claims are therefore also patentable over WO '084 for at least the reasons that claim 1 is patentable.

Claims 26, 28, 32-34, 45, 46, 51, and 116 stand rejected under 35 U.S.C. §103 as being unpatentable over WO '084. For at least the reasons that follow, withdrawal of the rejection is in order.

To establish a *prima facie* case of obviousness, the prior art references (or references when combined) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In addition, "all words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385; 165 USPQ 494, 496 (CCPA 1970). See M.P.E.P. §2143.03.

As explained above, Applicants submit that WO '084 fails to teach or suggest all of the claim elements. That is, because WO '084 fails to teach or suggest a

cosmetic or dermatological method for treating sensitive skin by topically applying to said sensitive skin having such amount of substance P already released therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance, WO '084 does not teach or suggest all of the elements of independent claim 116. (Emphasis added.) Again, Applicants submit that the skin being treated in WO '084 cannot be shown to necessarily have an "amount of already released substance P," as claimed.

Furthermore, WO '084 does not reflect a proper consideration of "all words" in the claim. In particular, because WO '084 does not teach or suggest a method comprising topically applying to sensitive skin having an amount of substance P already released therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P, Applicants submit that the rejection over WO '084 does not give full consideration to all of the claim elements, i.e., patentable weight must be given to "having such amount of substance P already released therein," "by exposure to and contact with at least one substance P-releasing active agent," and "an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P," in claim 116 in judging the patentability of claim 116 over WO '084.

Finally, as discussed above, Applicants submit that the §103 rejection over WO '084 should be withdrawn for at least the additional reason that WO '084 is directed to antagonizing binding or interaction of substance P with NK₂ receptors, which are not present in the skin. Thus, WO '084 cannot be relied on to support the

§103 rejection because the compositions described thereon would not be effective to treat sensitive skin.

For at least these reasons, claim 116 is patentable over WO '084. In addition, as explained above because the remaining claims depend, directly or indirectly from independent claim 116, the remaining claims are also patentable over WO '084 for at least the reasons that claim 116 is patentable.

Claims 26, 28-50, 53-54 and 116 stand rejected under 35 U.S.C. §103 as being unpatentable over Wallengren (Contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252 and/or WO 93/14084. For at least the reasons that follow, withdrawal of the rejection is in order.

As explained above, in order to establish a *prima facie* case of obviousness, it is necessary to demonstrate that the prior art references (or references when combined) teach or suggest all of the claim elements. See In re Royka. Additionally, "all words in a claim must be considered in judging the patentability of that claim against the prior art." See In re Wilson and M.P.E.P. §2143.03.

Applicants submit that a *prima facie* case of obviousness has not been established in view of the above-asserted combination of references. That is, Applicants submit that the above-asserted combination does not teach or suggest all of the elements of independent claim 116. Specifically, the above-asserted combination does not disclose or suggest a cosmetic or dermatological method for treating sensitive skin by topically applying to the sensitive skin having an amount of substance P already released therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released

substance P. (Emphasis added.) Additionally, the above-asserted combination does not reflect a proper consideration of "all words" in claim 116. That is, the words "having such amount of substance P already released therein," "by exposure to and contact with at least one substance P-releasing active agent," and "an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P," must be considered in judging the patentability of claim 116 over the combination of Wallengren (Contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO '252 and/or WO '084.

For at least these reasons, claim 116 is patentable over the combination of Wallengren (Contact Dermatitis), Wallengren (Br. J. Dermatitis) in combination with WO '252 and/or WO '084. In addition, as the remaining claims depend, directly or indirectly, from independent claim 116, Applicants submit that these claims are also patentable over the above-asserted combination for at least the reasons that claim 116 is patentable.

As a final matter, Applicants have added new Claim 121 to further define an exemplary embodiment. Applicants submit that, in addition to the reasons stated above, new Claim 121 is further distinguished from the cited prior art because it excludes "itching" and "pruritus" as symptoms of the sensitive skin being treated. Applicants believe that Claim 121 more clearly demonstrates that the claimed method is directed to the treatment of sensitive skin, which was demonstrated in the May 29, 2002, interview in the parent application to be substantially different from the allergic and/or immunological disorders being treated in the cited prior art references.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a notice of allowance. If there are any questions concerning this paper or

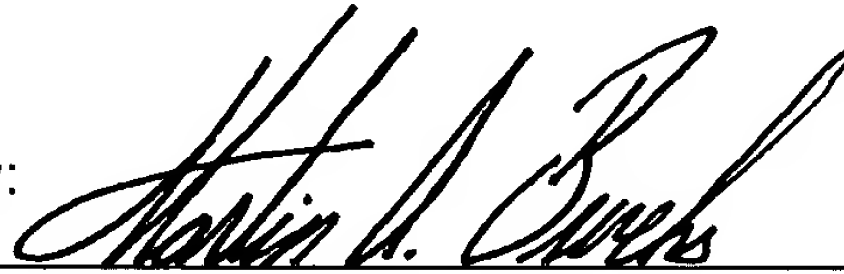
the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: April 20, 2005

By:

A handwritten signature in black ink, appearing to read "Martin A. Bruehs", written over a horizontal line.

Martin A. Bruehs

Registration No. 45,635

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620